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(54) Title: INSERTER HAVING BISTABLE EQUILIBRIUM STATES

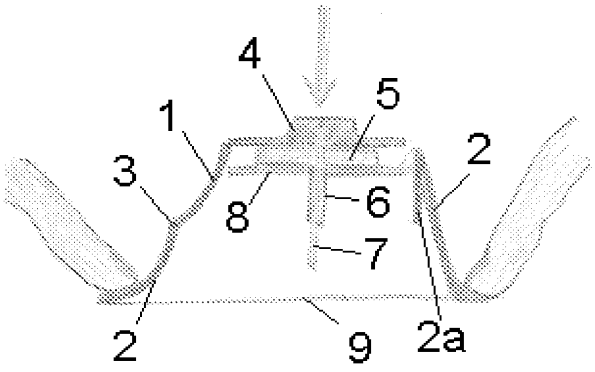

Fig. 1b

(57) Abstract: The invention relates to an inserter for an infusion set for intermittent or continuous administration of a therapeutical substance, such as e.g. insulin. The inserter comprises means for insertion and retraction of an introducer needle. With an inserter device according to the invention it is possible to introduce an insertion needle when placing a medical device sub- or transcutaneously. The Inserter device comprises a housing (1, 2, 12) which hides the insertion needle (7, 17) before insertion and can hide the insertion needle (7, 17) after insertion and placing of the medical device. The insertion needle (7, 17) moves relative to the housing (1, 2, 12) toward the patients skin surface during insertion and the inserter device comprises a bi-stable elastic element (1, 11) having two equilibrium states.

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Inserter having bistable equilibrium states

Technical field

The invention relates to an inserter for an infusion set for intermittent or continuous administration of a therapeutical substance, such as e.g. insulin. The inserter comprises means for insertion and retraction of an introducer needle.

Background of the invention

It is known to construct inserters for infusion sets which hides and protects the insertion needle before insertion and which retracts the insertion needle after penetration of the patients skin and thereafter hides and protects the insertion needle.

Such a device is known from EP 1.762.259. The inserter according to this document comprises a needle hub comprising an insertion needle and two spring units assuring automatic insertion and automatic retraction of the insertion needle. Although the design of the device is compact and user friendly the mechanism is relatively complex and provided with parts which have to move in relation to each other.

The present invention provides both protection of the insertion needle before insertion and after retraction and at the same time the inserter device is of a very simple construction which makes it both non-expensive to produce and reliable.

Another device is known from US 2004/0116865 A1. This document relates to a needle insertion device comprising a housing with a mounting surface adapted for application to the skin of a subject where the mounting surface defines a general plane and has a needle aperture formed therein. A needle comprises a distal pointed end adapted to penetrate the skin of the subject,

the pointed end being arranged within the housing in respect of the general plane. The mounting surface surrounding the needle aperture is moveable a first and a second position, in the first position the pointed end of the needle is arranged within the housing and in the second position the pointed end of the needle projects through the needle aperture as the skin portion corresponding to the intended injection site of the needle is pulled against the needle. According to this device the injection needle is stationary relative to the housing and the bi-stable member moves the skin in stead of the injection needle.

Summary of the invention

The present invention relates to an inserter device used to introduce a penetrating member into a patients skin when placing a medical device sub- or transcutaneously. The inserter device comprises a housing which hides the insertion needle before insertion and which housing might also hide the insertion needle after insertion and placing of the medical device, and where the insertion needle moves relative to the housing toward the patient's skin surface during insertion. The inserter device comprises a bi-stable elastic element having two equilibrium states.

Elastic elements are devices which can store elastic potential energy due to some kind of deformation e.g. due to either compression or stretching, and a force is required to deform an elastic element. An equilibrium state is a state where an elastic element is in equilibrium and has no incitement to move, although the elastic element has no incitement to move it might have a considerable potential energy which energy can be released if the elastic element is given a push away from the equilibrium state; if an elastic element is bi-stable it will have two such equilibrium states. If an elastic element having two equilibrium states is prevented from reaching a first and closest equilibrium state it will shift from trying to reach this equilibrium state and try to reach a second equilibrium state. A bi-stable elastic element can be a

single unloaded piece of material which can jump between two equilibrium states or a bi-stable elastic element can be a single loaded piece of material which due to the loading gets in a state where it can jump between two equilibrium states. The bi-stable elastic element can also be constructed of several individual pieces of material which pieces together form a single loaded or unloaded bi-stable elastic element.

A helical coil spring is an example of an elastic element which can normally not be used in connection with the present invention as such a spring only has one equilibrium state, when the spring is deformed it always tries to return to this one equilibrium state whether the deformation is a reduction or an extension of the spring.

According to one embodiment the first equilibrium state is found in a retracted position where the insertion needle and/or the cannula is protected from the surroundings and the second equilibrium state is found in a forward position where the insertion needle and/or the cannula extends from the housing.

According to one embodiment the elastic element forms part of the outer surface of the housing of the inserter device.

According to another embodiment the bi-stable elastic element is constituted of a flexible piece of material having two opposite ends which ends are held stationary – although the ends can be pivoted - relative to the house at a constant distance which is shorter than the length of the elastic element when being in an unloaded state.

According to one embodiment the elastic element can be brought from one position to the other position by activating means.

As the inserter device is of a simple and non-expensive construction the inserter device is normally disposable i.e. the inserter device is for single-use.

Often the device to be inserted is an infusion part comprising a through going opening and a cannula or the device to be inserted can be a sensor part comprising a sensor for sub- or transcutaneous positioning.

Normally the medical device comprises an adhesive proximal surface for fastening of the medical device to the skin of the patient. The adhesive proximal surface can be constituted by the proximal surface of a separate mounting pad being unreleasably fastened to the body of the medical device.

According to one embodiment the medical device is provided with a hard self-penetrating cannula and according to another embodiment the inserter device is provided with a penetrating insertion needle and the medical device is provided with a soft cannula.

Description of the drawings

Fig. 1a, 1b and 1c show an embodiment of an inserter according to the invention comprising a housing of bi-stable character carrying the medical device to be inserted.

Fig. 2a and 2b show another embodiment of an inserter comprising a housing of bi-stable character carrying the medical device to be inserted.

Fig. 3a, 3b and 3c show a third embodiment of an inserter comprising a bi-stable elastic element having the form of a flat curved material and fig. 3d shows an enlarged view of the cannula part of the port-device of this embodiment.

Fig. 4a and 4b show a view of the inside mechanism of the third embodiment.

The embodiment of fig. 1a, 1b and 1c comprises an elastic element 1 which element also forms part of the housing of the inserter device. The elastic element 1 is connected to a housing part 2 via links 3. The elastic element 1 is provided with a needle hub 4 in which an insertion needle 7 is embedded. Fig. 1b is a cut-through view of the embodiment of fig. 1a, and this view shows the port-device which is secured to the elastic element 1 in a position ready for insertion. The port-device shown in fig. 1 comprises a body 5 provided with a through-going opening and a cannula 6 fastened unreleasably to the body 5 of the port-device and extending from the proximal side of the body 5, i.e. the proximal side of the port-device is the side which will be facing the patients skin when the device is mounted on the patient. According to this embodiment the port-device is only secured to the elastic element 1 by the friction between the insertion needle 7 and the cannula 6 of the port-device but if for example the port-device was of a type provided with a hard cannula e.g. of steel which need no insertion needle to cut through the patients skin then the port-device could be secured to the inserter device e.g. by providing a protruding part on the proximal surface of the elastic element 1 which could be squeezed into a corresponding shaped hollow in the body 5 of the port-device and kept in position as a result of the friction between the sides of the body 5 of the port-device and at least part of the sides of the protruding parts of the elastic element 1.

The elastic element 1 is made of a relatively thin material which is the reason why the position of the needle hub 4 can be seen at the outer surface of the inserter device. The protrusion on the surface indicates where the needle hub 4 and the port-device are positioned and therefore the protrusion can be used as an activation button. If the elastic element was made of a thicker material it might be necessary to provide the inserter device with an actual activation button indicating the correct position for applying pressure.

The proximal circumference of the housing part 2, i.e. the part of the housing part 2 being in contact with the patients skin is stationary i.e. it does not move during use. The housing part 2 which is above the contact surface and which forms part of the links 3 can bend away from the centre of the inserter, the housing part 2 is made of a continuous material which can be bend without breaking i.e. the material is not brittle but flexible.

When the inserter device is to be used it is first removed from a sterile packing. The embodiment of the inserter of fig. 1a and 1b can conveniently be delivered having the port-device secured to the needle hub 4 of the inserter device. The inserter device is then placed against the patients skin at a suitable position and held at that position with two fingers as indicated in fig. 1b (right). Then the needle hub 4 is pushed down as indicated with the arrow in fig. 1b. When pushing down the elastic element 1 is deformed changing the angle α (indicated at fig. 1c) from around 90° to around 180°, the elastic element is forced out of the first equilibrium state and attempt to reach the second equilibrium state. The deformation of the elastic element 1 is like a jump from a first condition to a second condition therefore the light pressure on the activation button causes a fast deformation which results in the insertion needle 7 being "shot" into the patient. After the pressure is removed from the activation button the elastic element jumps back into the first equilibrium state and retracts the insertion needle 7 from the patient and the port-device. The retraction is due to that the second equilibrium state is never reached as the elastic element hits the patient's skin before reaching the second equilibrium state. As the elastic element 1 can only be kept stationary in the two equilibrium states the elastic element is said to be bi-stable.

Fig. 2a and 2b show another embodiment of an inserter device according to the invention. This embodiment also comprises an elastic element 1 forming part of the outer surface housing of the inserter device. The reference

numbers refer to the same parts as in fig. 1a and 1b. The port-device shown in fig. 2 comprises a body 5 provided with a through-going opening and a cannula which is also a penetrating member 7 fastened unreleasably to the body 5 of the port-device and extending from the proximal side of the body 5, when the device is mounted on the patient. According to this embodiment the port-device can be secured to the elastic element 1 by structures provided in the needle hub 4 for example the needle hub 4 can be provided with one or more protruding members which fits into closely corresponding openings in the distal surface of the body 5 of the port-device.

The embodiment of fig. 2 is activated and works in the same manner as described for the embodiment of fig. 1.

Fig. 3a, 3b and 3c show a third embodiment of an inserter device according to the invention. This embodiment also comprises a bi-stable elastic element 11 which element is placed inside a housing 12. The elastic element 11 is retained in position by placing the rounded ends of the elastic elements 11 in recesses 13 in opposite walls of the housing 12. The distance between the walls of the housing where the ends of the elastic elements are positioned is shorter than the length of the flexible piece of material constituting the elastic element 11. A needle hub 14 is fastened to a central part of the elastic element 11, and an insertion needle 17 is embedded in the needle hub 14 in such a way that the insertion needle is unreleasably fastened to the needle hub 14 e.g. the insertion needle is embedded during moulding. The inserter device is provided with an activation button 23 which activation button 23 is mounted in such a way that a protruding part 24 of the activation button 23 is in contact with the elastic element 11, especially the protruding part 24 touches the elastic element 11 when it is activated i.e. when it is forced out of the equilibrium state. A pair of guiding members 25 is fastened to the housing 12 in order to control the movements of the elastic element 11 when moving from the retracted position to the forward position. The guiding members 25

are placed parallel in an upright position on each side of the elastic element 11 and covers the full length of the path along which the elastic element 11 moves.

The device which is to be inserted with this embodiment of the inserter device is a port-device in combination with a separate cannula part. Fig. 3d shows the cannula part in an enlarged version. The port-device comprises a body 15 made of a relatively hard material and the cannula part comprises a body 20 of a relatively hard material, a septum 22 preventing access of microorganisms to the inner opening and a cannula 16 made of a soft and flexible material. Further the cannula part comprises locking parts 21 which secure the cannula part in the desired position in the body 15 of the port-device. The cannula part and suggested embodiments of the locking parts 21 are described in detail in PCT/DK2006/000737 and the relevant parts of this application is incorporated herein by reference. The body 15 might be provided with a mounting pad 18 unreleasably fastened to the body 15 or the mounting pad 18 might be provided in a separate packing and attached to the patients skin before the inserter device is positioned on the insertion site. If the mounting pad 18 is unreleasably fastened to the body 15, the layer protecting the adhesive surface should be removed before use, and then the adhesive surface of the mounting pad 18 is placed on the patients skin together with the inserter device.

As the elastic element 11 is curved and under tension it only has two stationary positions i.e. two equilibrium states, a retracted position where the insertion needle and cannula are protected from the surroundings and a forward position where the insertion needle 17 and the cannula 16 is placed sub- or transcutaneously. As the bi-stable elastic element 11 never reaches its complete resting position in the forward position as the volume of the needle hub 14 and the body 15 of the device to be inserted prevents this, the elastic element 11 will after having been activated in the retracted position

and attempted to reach the forward position, automatically jump back into the retracted position and leave the cannula device in the body 15 of the port-device as the locking parts 21 of the cannula part connects with corresponding parts in the port device and will prevent the cannula part from being withdrawn together with the elastic element 11 and the needle hub 14.

When the inserter device is to be used it is first removed from a sterile packing. According to the present embodiment the port-device might either be delivered together with inserter device positioned in a shaped hollow in the proximal end of the inserter device while the cannula part is attached to the insertion needle, or the port-device might be delivered separate and fastened to the skin of the patient by the mounting pad 18 before use of the inserter device. The inserter device is placed against the patients skin before or after placing the port-device together with the mounting pad 18 at a suitable position and held at that position. Then the activation button 23 is pushed toward the centre of the housing 12. When activating the activation button 23 the protruding part 24 pushes the elastic element 11 out of the first resting position, i.e. the retracted position. When pushing the activation button 23 forward the activation button is broken off at its fixation point on the elastic element 11. This feature prevents repeated activation of the inserter device which could cause problems or discomfort as the now probably contaminated insertion needle 17 would jump out of the housing and expose the surroundings to skin penetration and possibly infections.

Claims

1. Inserter device used to introduce an insertion needle (7, 17) when placing a medical device sub- or transcutaneously, which inserter comprises a housing (1, 2, 12) which hides the insertion needle (7, 17) before insertion and can hide the insertion needle (7, 17) after insertion and placing of the medical device, and where the insertion needle (7, 17) moves relative to the housing (1, 2, 12) toward the patients skin surface during insertion **characterized in** that the inserter device comprises a bi-stable elastic element (1, 11) having two equilibrium states.

2. Inserter device according to claim 1, **characterized in** that one equilibrium state is in a retracted position where the insertion needle (7, 17) and/or the cannula (6, 16) is protected from the surroundings and the second equilibrium state is in a forward position where the insertion needle (7, 17) and/or the cannula (6, 16) extends from the housing (2, 12).

3. Inserter device according to claim 1 or 2, **characterized in** that the insertion needle (7, 17) is secured to the elastic element (1, 11).

4. Inserter device according to claims 1, 2 or 3, **characterized in** that the elastic element (1) is a part of the outer surface of the housing of the inserter device.

5. Inserter device according to claims 1, 2 or 3, **characterized in** that the elastic element (1, 11) is constituted of a flexible piece of material having two opposite ends which ends are held stationary relative to the house at a distance shorter than the length of the elastic element in a stretched or unloaded state.

6. Inserter device according to any preceding claim, **characterized in** that the elastic element (1) can be brought from one position to the other position by activating means (23).

7. Inserter according to any of the preceding claims, **characterized in** that the inserter device is disposable i.e. the inserter device is for single-use.

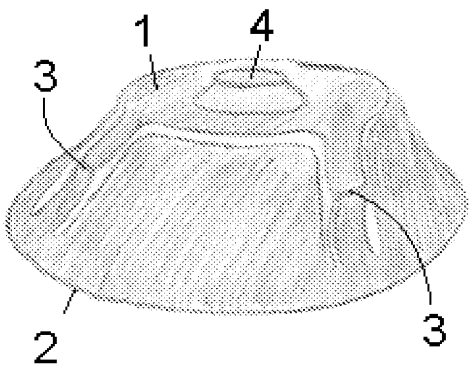
8. Inserter according to any of the preceding claims, **characterized in** that the medical device to be inserted is an infusion part comprising a through going opening and a cannula.

9. Inserter according to any of the claims 1-7, **characterized in** that the device to be inserted is a sensor part comprising a sensor for sub- or transcutaneous positioning.

10. Inserter according to any of the preceding claims, **characterized in** that the medical device comprises an adhesive proximal surface for fastening of the medical device to the skin of the patient.

11. Inserter according to any of the preceding claims, **characterized in** that the medical device is provided with a hard self-penetrating cannula.

12. Inserter according to any of the claims 1-10, **characterized in** that the inserter device is provided with a penetrating insertion needle (7, 17) and the medical device is provided with a soft cannula (6, 16).



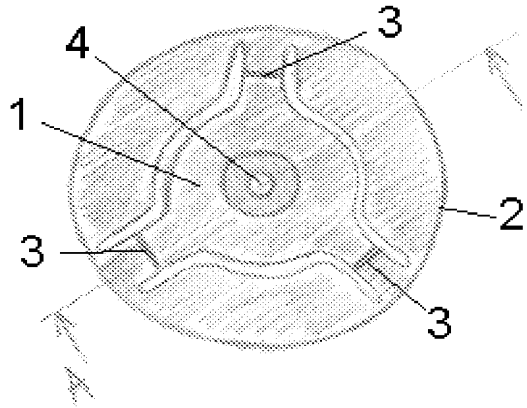
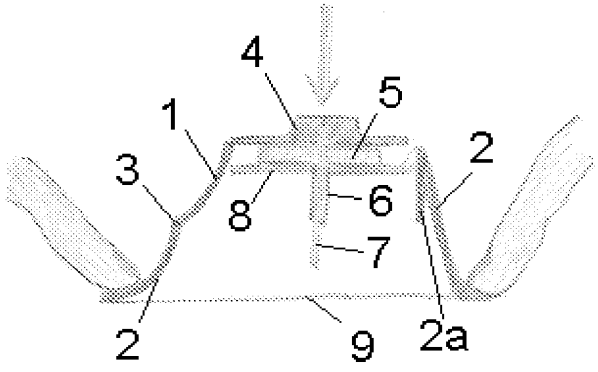


Fig. 1a



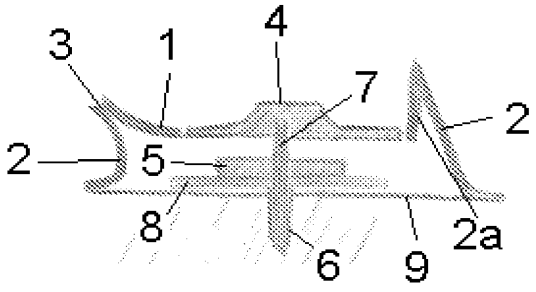


Fig. 1b

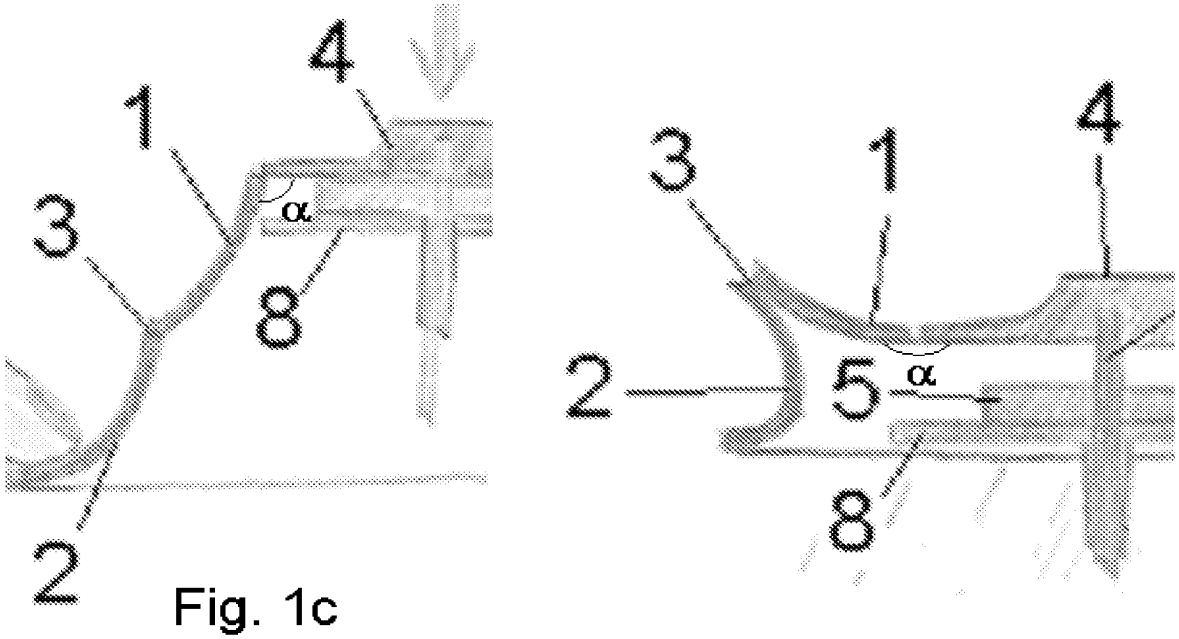


Fig. 1c

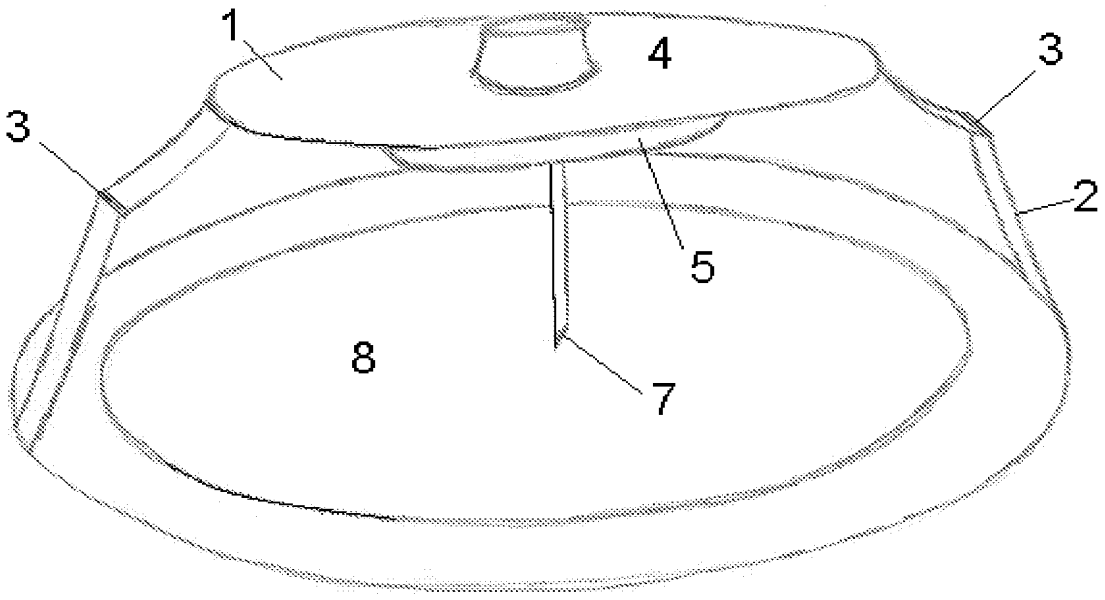


Fig. 2a

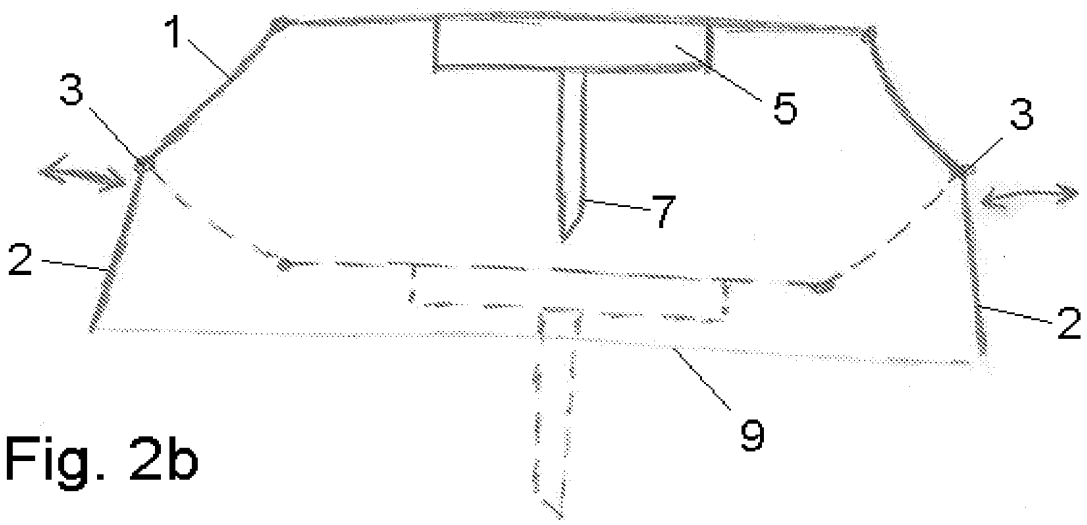


Fig. 2b

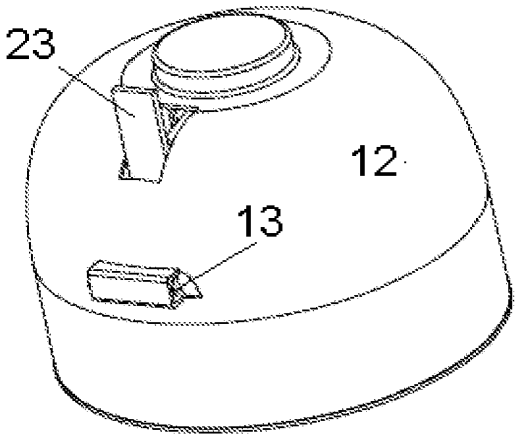


Fig. 3a

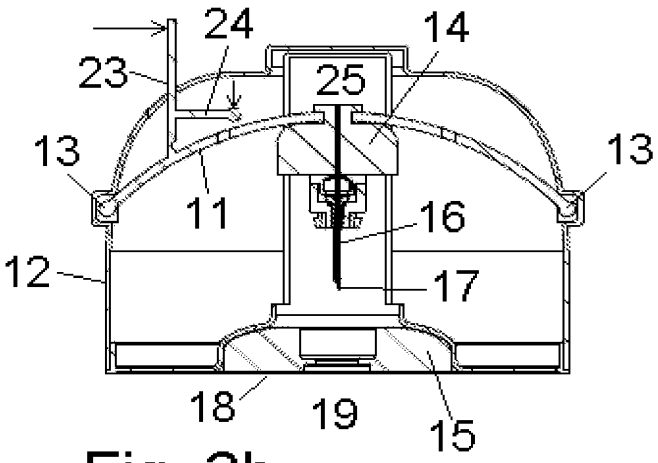


Fig. 3b

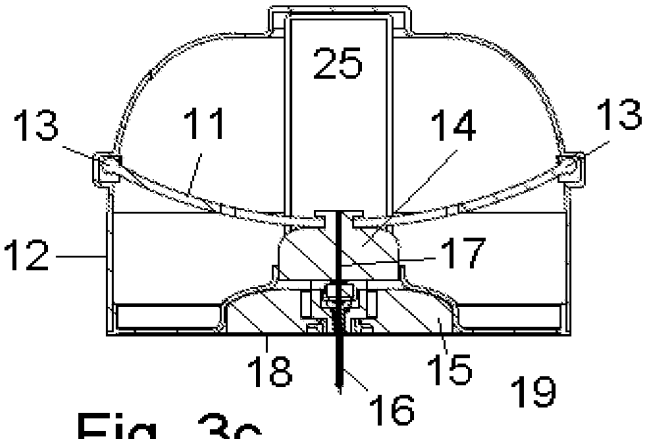
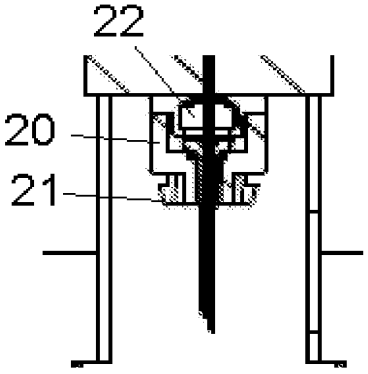


Fig. 3c



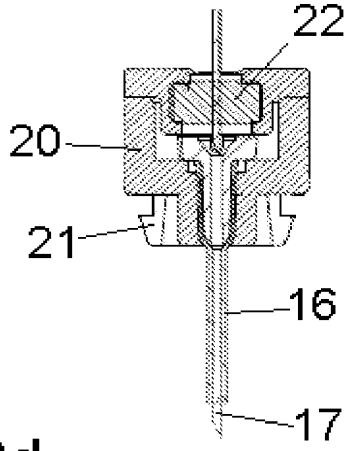


Fig. 3d

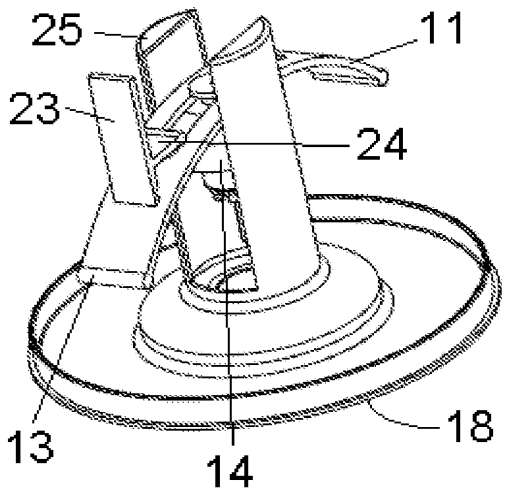


Fig. 4a

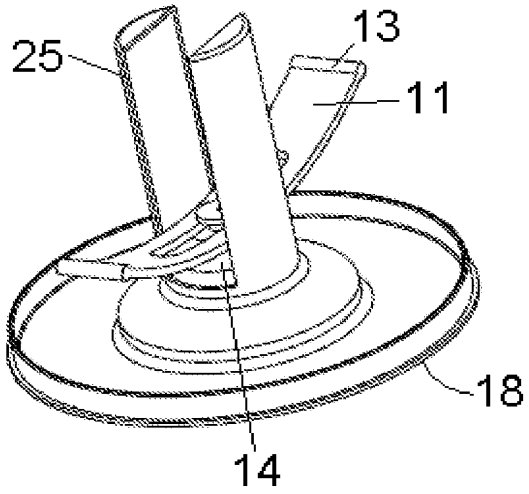


Fig. 4b

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/058500

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32 A61M5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/76684 A (INSULET CORP [US]) 18 October 2001 (2001-10-18) figures 1-5 page 6, line 23 - page 8, line 28	1-8, 10-12
X	US 2002/022798 A1 (CONNELLY ROBERT I [US] ET AL) 21 February 2002 (2002-02-21) figures 1-13 paragraph [0034] - paragraph [0059]	1,2,4-8, 10
A	US 2004/116865 A1 (BENGTSSON HENRIK [DK]) 17 June 2004 (2004-06-17) cited in the application figures 1-7 paragraph [0051] - paragraph [0053] paragraph [0057] - paragraph [0064] claims 1-8	1-12

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 October 2008	05/11/2008

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/058500

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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